

**REMARKS**

The Examiner is thanked for the due consideration given the application.

Claims 1-5 and 9-17 are pending in the application. Claims 9-17 are newly presented. It is noted that claims 6-8 were presented in the original WIPO application (WO 03/079816), but only claims 1-5 were present in the EPO annex date April 15, 2004.

Claims 1 and 2 have been amended to improve their language. New claims 9-11 find support in the specification at page 2, lines 15-17. New claim 12 finds support in the specification at page 3, line 28. New claims 13-15 finds support in the specification at page 2, lines 18-24. New claim 16 finds support in the specification at page 2, lines 25-27. New claim 17 finds support in the specification at page 3, lines 8-9.

No new matter is believed to be added to the application by this amendment.

**Rejection Under 35 USC §112, Second Paragraph**

Claims 1-5 have been rejected under 35 USC §112, second paragraph as being indefinite. This rejection is respectfully traversed.

The Official Action asserts that the term "tomato whole extract" in claim 1 is unclear. However, this term has been amended to read "whole tomato extract."

The Official Action asserts that it is unclear in claim 1 regarding what part of the concentrate is further used. However, one of ordinary skill would recognize that the simplest course of action would probably be to extract the whole concentrate. However, variations of this step may be used depending on the results of the concentration step.

The Official Action asserts that line 1 of claim 2 is unclear. However, the copy of the claims on PAIR (as noted during a search on May 29, 2008) indicates that line 1 of claim 2 has been smudged by the Office, as is reproduced below.

**2) A process as claimed in claim 1, wherein the concentration of the extract according to step e) is carried out to a final volume ranging from 0.10 to 0.28% with respect to the starting volume, further comprising the following steps:**

However, it is noted that line 1 of claim 2 reads: "A process as claimed in claim 1, wherein the concentration of the extract . . . ."

Claim 2 has also been amended to improve the antecedent basis.

The claims are thus clear, definite and have full antecedent basis.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

**Rejections Under 35 USC §103(a)**

Claims 1 and 5 have been rejected under 35 USC §103(a) as being unpatentable over AUSICH et al. (U.S. Patent 5,858,700)

in view of KAGAN (U.S. Publication 2003/0044495) and SCHAAP (WO 03/08064). BOMBARDELLI et al. (EP 0818 225) has been added to the aforesaid rejection to reject claims 2-4. These rejections are respectfully traversed.

The present invention pertains to a process for the preparation of whole tomato extracts with lycopene content from 5% to 20% and with reducing sugars content expressed as glucose lower than 1%. The process includes the following steps:

- a) pretreating fresh tomatoes, which includes washing, then cutting or crushing;
- b) heat concentrating of the cut or crushed tomatoes from step a);
- c) extracting the concentrate from step b) with water-saturated ethyl acetate;
- d) backwashing the extract from step c) with water; and
- e) concentrating the extract to dryness under reduced pressure.

AUSICH et al. pertain to a process for producing lycopene crystals from a lycopene-containing oleoresin, which avoids the use of added organic solvents (see AUSICH et al. at col. 2, lines 25-35 and 57-60). The starting material for this process is an oleoresin, which can in turn be obtained from a carotenoid source, such as tomatoes.

However, AUSICH et al. teach that tomato skins, paste and pomace can indifferently be used for the preparation of the

oleoresin and that hexanes are the preferred solvents (see AUSICH et al. column 6, lines 9-14 and 21-31). In contrast, claim 1 of the present invention uses "fresh tomatoes."

In AUSICH et al., ethyl acetate is only mentioned in an exemplary list of solvents which can be used for extracting carotenoids from biological sources. Therefore, since AUSICH et al. relate to the preparation of pure lycopene crystals, while the present application concerns the preparation of whole tomato extracts enriched in lycopene and with a low sugar content, a skilled person would not consider AUSICH et al. because the reference is non-analogous art.

Further, AUSICH et al. fails to disclose or infer:

- choosing whole tomatoes as the lycopene source;
- using whole tomatoes as starting materials;
- replacing hexanes with water-saturated ethyl acetate; and
- carrying out a backwashing step with water.

Further, in Examples 1-3 of AUSICH et al. tomato skins and dried paste are used as source of lycopene. Although the title of Example 3 mentions fresh tomatoes, the example itself teaches to isolate the skins, dry them and extract them with hexanes (see AUSICH et al. at col. 12, line 67 to col 13, line 15), so the actual source of lycopene is the skin.

Concerning the backwashing step with water, the Official Action asserts that the sugar content in the extract of

AUSICH et al. is lower than 1%, due to the fact that the **lycopene paste oleoresin** "has been washed."

However, the process of the present invention is carried out on **whole** tomatoes, not on a tomato oleoresin. Moreover, AUSICH et al. mentions washing **skin extract** with water in a passage (see AUSICH et al. at column 10, lines 45-49) which provides a brief explanation of the AOAC method for determining lycopene concentration in a carotenoid source, where water is used only for washing out acetone before extraction with hexanes; and for extraction, only hexanes are used. In view of this, there is no basis in AUSICH et al. to support the assertion that the amount of reducing sugar must be lower than 1%.

The Official Action also asserts that replacing hexanes with ethyl-acetate would have required only routine experimentation or that it would have been suggested by SCHAAP et al. or KAGAN.

However SCHAAP et al. does not pertain to the preparation of a tomato whole extract, but the fermentative production of lycopene by *B. trispora* and the preparation of a crystalline compound, where ethyl acetate can be used for separating lycopene from the mycelium and no backwashing is required.

Further, SCHAAP et al. mentions ethyl acetate, not "water-saturated ethyl acetate," as is set forth in claim 1 of the present invention (Example 8 of SCHAAP et al., in particular,

teaches to dry the cake obtained from the fermentation broth and to extract it with ethyl acetate, without backwashing).

In the present invention, the use of water-saturated ethyl acetate allows maximization of the extraction of lycopene while keeping the amount of extracted sugars low, and the backwashing step with water further diminishes the sugar content. This unexpected result was not predictable from SCHAAP et al. or from any of the other applied prior art documents.

Therefore, a skilled and creative person would not have turned to SCHAAP in order to prepare a whole tomato extract with a content of reducing sugars lower than 1% and even if one skilled in the art had come across this document, he/she would not have selected ethyl acetate as solvent, replaced it with water-saturated ethyl acetate and carried out a backwashing step.

Regarding KAGAN, the Official Action asserts that this document discloses the use of water and ethyl acetate as solvents in the extraction of carotenoids and lycopene. However, the Official Action overlooks that KAGAN also requires a water-soluble co-solvent so that the resulting multiphase system will necessarily include two phases, one mainly aqueous and the other mainly non-aqueous or oily. There is nothing in KAGAN which would have suggested a skilled person to:

- avoid the use of a water-soluble co-solvent, and
- select water-saturated ethyl acetate as hydrophobic solvent.

Further, KAGAN pertains to the extraction of carotenoids from biomass but, despite mentioning lycopene among carotenoids and tomatoes among biomasses, it is focused in particular with the extraction of astaxantin from *P. rodozyma*.

The teachings of BOMBARDELLI et al. (applied to reject claims 2-4) fail to address the above-described deficiencies of AUSICH et al., KAGAN and SCHAAP.

One of ordinary skill and creativity would thus fail to produce claim 1 of the present invention from a knowledge of the applied art references. A *prima facie* case of unpatentability has thus not been made. Claims depending upon claim 1 are patentable for at least the above reasons.

Further, the present invention shows unexpected results, discussed above, that would rebut any unpatentability that could be alleged.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

#### **New Claims 9-17**

Claims 9-17 have been newly presented for consideration on the merits. It is believed that claims 9-17 are instantly patentable at least for the reasons set forth above.

#### **Conclusion**

The Examiner is thanked for considering the Information Disclosure Statement filed September 24, 2004 and making initialed PTO-1449 Form of record in the application.

Prior art of record but not utilized is believed to be non-pertinent against the claims.

The rejections are believed to be overcome, obviated or rendered moot, and no issues remain.

The Examiner is respectfully requested to place the application to place in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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Robert E. Goozner, Reg. No. 42,593  
Customer No. 00466  
209 Madison Street, Suite 500  
Alexandria, VA 22314  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

REG/lad